SCE 0907 Public Evidence Appendix

Bias and transparency

Literature review date: September 13, 2026

Controlling principle. Bias is systematic distortion rather than random uncertainty. Credibility depends on the combined pattern of design safeguards, execution, prespecification, complete reporting, transparency, and disclosure—not on labels such as randomized, peer-reviewed, industry-funded, academic, positive, or negative.

Point-by-point framework

Controlling Point	Primary risk	Key safeguards / boundary
Selection bias	Systematic differences in who enters a study or receives each intervention.	Randomization, allocation concealment, careful eligibility and confounding control; baseline similarity alone does not prove absence of bias.
Performance bias	Differences in care, attention, co-interventions, monitoring, or behavior after assignment.	Blinding when feasible and standardized background care, rescue therapy, rehabilitation, and follow-up.
Detection bias	Knowledge of assignment influences outcome measurement, adjudication, or recording.	Blinded assessment, central review, standardized definitions, objective measures, and independent adjudication.
Attrition bias	Withdrawal, loss to follow-up, discontinuation, or missing outcomes distort comparison.	Participant-flow reporting, prevention of loss, ITT principles, appropriate missing-data methods, and sensitivity analyses.
Selective reporting	Outcomes, time points, subgroups, analyses, or harms are emphasized according to results.	Prospective registration, protocols, analysis plans, complete reporting, and transparent labeling of post hoc analyses.
Sponsorship bias	Funder or sponsor interests influence design, analysis, interpretation, or publication.	Disclose funding, conflicts, sponsor roles, investigator data access, analytic responsibility, and publication rights.
Publication bias	Study visibility depends on direction, significance, or novelty of results.	Registration, results posting, regulatory disclosure, unpublished-evidence searches, and inclusion of negative/inconclusive evidence.

Evidence-handling rules

Positive, negative, mixed, null, and inconclusive studies receive the same bias assessment. Funding source is neither proof of validity nor proof of invalidity; sponsor influence must be evaluated through disclosed roles, design, data access, analysis, reporting, and publication rights.

For cell and extracellular-vesicle studies, transparent reporting of tissue source, culture, purification, storage, potency, dose, lot, procedure, rehabilitation, background care, and center expertise is part of bias assessment because hidden heterogeneity can materially affect results.

Principal references

1. 1. Sterne JAC, Savovi■ J, Page MJ, et al. RoB 2: A revised Cochrane risk-of-bias tool for randomized trials. Cochrane Methods.

2. 2. Sterne JA, Hernán MA, Reeves BC, et al. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions. BMJ. 2016;355:i4919.

3. 3. CONSORT Group. CONSORT 2025 Statement and explanatory materials for randomized trials.

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5. 5. World Health Organization. International Clinical Trials Registry Platform and trial-registration standards.

6. 6. U.S. National Library of Medicine. ClinicalTrials.gov registration and results-reporting framework.

7. 7. Lundh A, Lexchin J, Mintzes B, Schroll JB, Bero L. Industry sponsorship and research outcome. Cochrane Database Syst Rev. Updated methodological evidence on sponsorship effects.

8. 8. Page MJ, Sterne JAC, Boutron I, et al. Bias due to selective inclusion and reporting of results in systematic reviews and related reporting-bias methodology.